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# 510(k) Summary of Safety and Effectiveness
# A.R.C. Phaco Pack I & II, Laser Pack I & II

**Regulatory Authority:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

**Manufacturer:**

A.R.C. Laser AG
St. Gallerstrasse 161
CH-8645 Jona
Switzerland

**Submitter/Contact Person**

Daniel Hoefer
A.R.C. Laser Corporation
2417 South 3850 West
Salt Lake City, UT 84120
TEL (801) 972 1311, FAX (801) 972 5251

**Name of Device:**

**Trade Name:** A.R.C. Phaco Pack I, Phaco Pack II, Laser Pack I, and Laser Pack II
**Classification Name:** Unit, Phacofragmentation

**Predicate Devices:**

The A.R.C.Phaco Pack I, A.R.C. Phaco Pack II, A.R.C. Photolysis Pack I, and A.R.C. Photolysis Pack II are substantially equivalent to the "Storz DP 4310"(Storz Instruments, K955901), the "Storz DP 5000" (Storz Instruments, K961874) and the AMO Prestige Day Pack (Allergan K962402).

**Description of Device:**

The A.R.C. Laser Pack I includes: Single-use Disposable Infusion tube set ("IOP Set"), Single-use Disposable aspiration tubing set, and single-use disposable laser photolysis handpiece (K993154).

The Laser Pack II includes: Single-use disposable infusion tubing set ("IOP Set"), single-use disposable aspiration tubing set, limited re-use collection cassette, overflow drainage bag, and single-use disposable laser photolysis handpiece (K993154).

The A.R.C. Phaco pack I includes: Limited re-use disposable silicone infusion sleeve (qty.2), limited re-use disposable test-chamber (qty. 2), single-use disposable infusion tubing set ("IOP Set"), and single-use disposable aspiration tubing set.

The A.R.C. Phaco Pack II includes: Limited re-use disposable silicone infusion sleeve (qty. 2), limited re-use disposable test chamber (qty. 2), single use disposable infusion tube set ("IOP Set"), single-use disposable aspiration tubing set, limited re-use disposable collection cassette, and overflow drainage bag.

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**Intended Use:**

The A.R.C. Phaco Pack I, Phaco Pack II, Laser Pack I and Laser Pack II are intended as accessories to a ~~phaco~~emulsification system, to be used in the phacofragmentation and aspiration of cataracts. phacoemulsification

**Device Comparison:**

The A.R.C.Phaco Pack I, A.R.C. Phaco Pack II, A.R.C. Photolysis Pack I, and A.R.C. Photolysis Pack II are substantially equivalent to the "Storz DP 4310"(Storz Instruments, K955901), the "Storz DP 5000" (Storz Instruments, K961874), and the AMO Prestige Day Pack (Allergan, K962402).

The intended use, materials, reusability, construction, surgical methods, instructions, cautions and warnings are all substantially the same. Each is a surgical kit/pack containing items intended for use as accessories in the phacoemulsification of cataracts and aspiration of fluids and emulsified lens material. Each contains both infusion tubing sets and aspiration tubing sets. Each contains a collection cassette and test chamber. Other items include drapes and infusion sleeves for use during cataract surgery. The A.R.C. Laser Pack I and Laser Pack II include the sterile disposable photolysis handpiece (K993154), also used as an accessory in cataract surgery.

| Substantial Equivalence; Phaco packs | | | | |
|---|---|---|---|---|
| Product | K-Number | Intended Use | Individual Pack Components | Reusable components |
| A.R.C. Phaco Pack I | Present, 993154 | Accessories for Phacoemul-sification of cataracts | Infusion tube set, Aspiration tube set, Silicone sleeve (2), Test Chamber (2) | Collection Cassette |
| A.R.C. Phaco Pack II | | | Infusion tube set, Aspiration tube set, Silicone sleeve (2), Test Chamber (2), collection cassette, drainage bag | |
| A.R. C. Laser Pack I | | | Photolysis Handpiece, Infusion tube set, Aspiration tube set, collection cassette, drainage bag | |
| A.R.C. Laser Pack II | | | Photolysis Handpiece, Infusion tube set, Aspiration tube set | |
| Storz DP4310 | K955901 | Phacoemul-sification | Anterior Collection Cassette, I/A test | No |

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|---|---|---|---|---|
| | | of cataracts | chamber, Needle Wrench, Infusion Sleeve, I/A tube assembly, BSS Administration tube assembly, Auxiliary Drape, Mayo Arm Drape, Male Luer Cap, Tube Stopper | |
| Storz DP5000 | K961874 | Phacoemul-sification of cataracts | Anterior Collection Cassette, I/A test Chamber, Needle Wrench, Infusion Sleeve, I/A tube assembly, BSS Administration Tube assembly | Yes, Anterior collection cassette, I/A test chamber, needle wrench, and Infusion sleeve |
| Allergan AMO Prestige Day Pack | K962402 | Cataract Extraction | Cartridge Assembly, I/A tubing, Drip Spike Assembly, Drain bag | Yes, I/A tubing, Drain Bag |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Mr. Daniel Hoefer
A.R.C. Laser Corporation
2417-South 3850 West
Salt Lake City, UT 84120

Re: K003512
Trade Name: A.R.C. Phaco Pack I and Phaco Pack II
A.R.C. Laser Pack I and Laser Pack II
Regulatory Class: Class II
Product Code: 86 HQC, Phacoemulsification Accessory Pack
79 GEX, Laser Instrument, Surgical, Powered
Regulation: 886.4670, Unit Phacofragmentation, System
878.4810, Laser Surgical Instrument
Dated: November 13, 2000
Received: November 14, 2000

Dear Mr. Hoefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David R. Whipple

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**510(k) Number (if known):** K003512

**Device Name:** A.R.C. Phaco Pack I and II, Laser Pack I and II

**Indications For Use:**

1. Accessories for a phacoemulsification system, to be used in the phaco fragmentation and aspiration of cataracts.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003512

**Prescription Use** X **OR Over-The-Counter Use** ____
**(Per 21 CFR 801.109)**

**(Optional Format**